

Applicants: Eric Rose, et al.  
Serial No.: 10/646,493  
Filed: August 21, 2003  
Page 4

**REMARKS**

Claims 9 and 38-44 are pending in the subject application. Applicants herein cancel claims 39-42 as withdrawn. Applicants have also amended claim 9 to more particularly point out that which the applicants regard as the invention. Applicants maintain that this amendment raises no issue of new matter. Accordingly, upon entry of this Amendment, claims 9, 38, 43 and 44 will be pending and under examination.

**Rejections under 35 U.S.C. §112, First Paragraph**

The Examiner rejected claim 9 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

Specifically, the Examiner alleges that the specification does not support or provide examples of an "anti-Factor IXa antibody or fragment thereof", "small organic molecules" and "peptidomimetics."

In response, and without conceding the correctness of the Examiner's rejection, applicants note that claim 9, as amended, does not recite the terms "anti-Factor IXa antibody or fragment thereof", "small organic molecules" and "peptidomimetics". Accordingly, the Examiner's rejection is overcome.

The Examiner further rejects claim 9 under 35 U.S.C. §112, first paragraph, as allegedly not enabled.

Specifically, the Examiner alleges that the specification does not

Applicants: Eric Rose, et al.  
Serial No.: 10/646,493  
Filed: August 21, 2003  
Page 5

reasonably provide enablement for a Factor IXa having a post-translational modification which is  $\gamma$ -carboxylation of glutamic acid.

In response, and without conceding the correctness of the Examiner's rejection, applicants note that claim 9, as amended, does not recite a Factor IXa having a post-translational modification which is  $\gamma$ -carboxylation of glutamic acid. Accordingly, the Examiner's rejection is moot.

#### **Benefit Claim Under 35 U.S.C. §120**

The Examiner asserted that claims 9, 38, 43 and 44 are not entitled to the benefit of the filing date of parent application PCT/US97/08282, as that application allegedly does not disclose, under the test of 35 U.S.C. §112, first paragraph, anti-Factor IX antibodies or fragments, small organic molecules, peptidomimetics, and the particular Factor IXa muteins recited in the claims.

Applicants acknowledge the Examiner's remarks, without conceding their correctness.

#### **Rejections under 35 U.S.C. §102(b) and (e)**

The Examiner rejected claim 9 under 35 U.S.C. §102(b), as allegedly anticipated by WO Patent Application No. 95/17421 ("the '421 application").

Specifically, the Examiner alleges that the '421 application teaches peptide analogs of human Factor IXa which compete with

Applicants: Eric Rose, et al.  
Serial No.: 10/646,493  
Filed: August 21, 2003  
Page 6

native Factor IXa for binding to a platelet surface, thereby inhibiting Factor IXa-induced activation of Factor X. The Examiner further alleges that these peptide analogs are free of  $\gamma$ -carboxylated glutamic acid residues and have an artificially introduced restricted conformation. Accordingly, the Examiner alleges that the peptide analogs correspond to the inactive mutein form of Factor IXa recited in claim 9.

In response, and without conceding the correctness of the Examiner's rejection, applicants note that the '421 patent does not teach any of the inactive mutein forms of Factor IXa recited in claim 9, as amended. Accordingly, the Examiner's rejection thereof is overcome.

The Examiner further rejected claim 9 under 35 U.S.C. §102(b), as allegedly anticipated by Larson, et al.

Specifically, the Examiner alleges that Larson, et al. teach a mutein of Factor IXa in which arginine occurs in place of glycine at position 12, and that the mutein is purified in Hepes-buffered saline, which corresponds to the pharmaceutically acceptable carrier recited in claim 9.

In response, and without conceding the correctness of the Examiner's rejection, applicants note that Larson, et al., does not teach any of the inactive mutein forms of Factor IXa recited in claim 9, as amended. Accordingly, the Examiner's rejection is overcome.

The Examiner further rejected claim 9 under 35 U.S.C. §102(b), as

Applicants: Eric Rose, et al.  
Serial No.: 10/646,493  
Filed: August 21, 2003  
Page 7

allegedly anticipated by Amparo, et al.

Specifically, the Examiner alleges that Amparo, et al. teach small organic molecules in the form of pharmaceutical compositions which inhibit the activity of Factor IXa.

In response, and without conceding the correctness of the Examiner's rejection, applicants note that claim 9, as amended, does not recite small organic molecules. Accordingly, the Examiner's rejection thereof is overcome.

Finally, the Examiner rejected claim 9 under 35 U.S.C. §102(e), as allegedly anticipated by Blackburn, et al.

Specifically, the Examiner alleges that Blackburn, et al. teach monoclonal antibodies which bind to Factor IXa and which inhibit Factor IXa activity.

In response, and without conceding the correctness of the Examiner's rejection, applicants note that claim 9, as amended, does not recite an anti-Factor IXa antibody or fragment thereof. Accordingly, the Examiner's rejection thereof is overcome.

#### **Claim Objection**

The Examiner objected to claims 38, 43 and 44 as being dependent upon a rejected base claim.

In response to the Examiner's objection, applicants maintain that claim 9, as amended, overcomes the Examiner's outstanding

Applicants: Eric Rose, et al.  
Serial No.: 10/646,493  
Filed: August 21, 2003  
Page 8

rejections, and that such rejections and objections should be withdrawn.

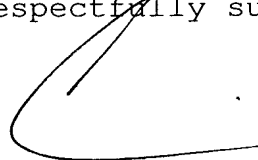
### Summary

For the reasons set forth hereinabove, applicants maintain that the pending claims are in condition for allowance, and respectfully request allowance.

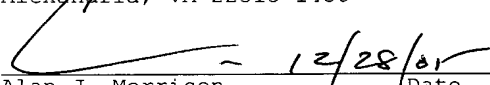
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
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